STUDY OF POST-SEPARATION HIV-POSITIVE SERVICEMEN LOST TO FOLLOW-UP

ANNUAL REPORT

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Study of Post-Separation HIV-Positive Servicemen Lost to Follow-up

(U.S. Army Medical R&D contract DAMD17-91-Z-1040)

During the first year of this contract, a number of activities were undertaken and preliminary work completed. The contract identifies six work areas: records follow-up: mortality data; records follow-up: morbidity data; records follow-up: CDC AIDS registry; contact and follow-up of HCBs; data management: security and confidentiality; and data analysis and dissemination. Each of these areas will be discussed in turn.

Records Follow-up: Mortality data

On 18 December 1991, the Medical Follow-up Agency (MFUA) wrote to the Chief Benefits Director (CBD) of the Department of Veterans Affairs (VA), requesting access to VA benefits records. On 15 January 1992, the CBD responded, granting the release to MFUA of identifying and claims file location information from the Beneficiary Identification and Records Locator Subsystem (BIRLS) and additional information in VA claims files on deceased veterans in the study.

A hard-copy list of 623 Army health care beneficiaries (HCB) lost-to-follow-up (LTFU) was provided to MFUA on 3 December 1991. Using this list, a 10% sample of names (N=71) was chosen to check VA mortality ascertainment procedures.

Because the number of subjects in the sample was small, the 71 subjects chosen were traced one by one in the BIRLS system rather than sent to the VA in a single batch for off-line computer processing. This was done not only because the one-by-one processing is faster for small samples, but also because the search algorithms for the one-by-one processing are more flexible than the batch processing algorithms, and the person doing the data input can customize the search to the particulars of each case. In fact, given these arguments, we anticipate that one-by-one searching will be used for the entire sample. In addition to vital status, address information was sought from the BIRLS file. The results of the pilot study were sent to WRAIR on April 27, 1992.

Briefly, the vital status results for the sample were as follows: 87.3% were alive (presuming those without BIRLS folder locations to be alive), 9.9% were dead, and 2.8% had no record on BIRLS. With respect to obtaining VA benefits records, deceased subjects and those with folder locations--in both situations these cases are easier to locate--accounted for 91.6% of the

sample. Subjects with no BIRLS record or no folder location--who are harder to trace--were 8.4% of the sample.

In the upcoming year, vital status will be obtained on all LTFU subjects and death certificates sought. An independent search of the National Death Index (NDI) will be done and the results of that search compared to the VA mortality ascertainment.

Records Follow-up: Morbidity data

To gain access to VA medical records, MFUA drafted a letter which was initially discussed and with reviewed by VA medical administration staff. After revision, the letter was sent to WRAIR, who then made the formal request for access to Dr. James Holsinger, Chief Medical Director (CMD) of the VA. After formal review to determine whether the computer file matching was allowable under the Computer Matching and Privacy Protection Act of 1988, the CMD granted access to the VA's automated hospital discharge file (the Patient Treatment File, PTF), in a letter dated 10 April 1992.

A data file containing records for LTFU subjects was received from WRAIR on 23 April 1992. These data were used to prepare two separate data files--one with identification data and one without--as outlined in our proposal. The separation of identification data from other data allows a more stringent control of access (see data management section).

To the data on the LTFU file were added several hundred "control" records, consisting of fictional Social Security Numbers (SSNs) assembled using SSN prefixes from subjects in another MFUA study files and randomly generated terminal digits. The inclusion of these bogus controls insures that the mere presence of an SSN on the file sent to the VA does not guarantee that the subject is an HIV-positive individual. The input file was sent to the VA Data Processing Center in Austin, Texas for processing. In September, the Patient Treatment File output was returned to MFUA.

In the upcoming year, the processing of the PTF records will begin. Hospitalization data from Army data files will also be obtained, and when a subject's permission is granted, morbidity records outside the federal system will be sought.

CDC AIDS Registry

After initial contact with CDC personnel, in which they indicated that access might not be granted to the CDC AIDS file, no further work has been done. A follow-up contact with CDC will be made in the upcoming year.

Contact and Follow-up of HCBs

Before attempting to contact the LTFU HCBs, it was necessary to obtain approval from the National Academy of Sciences' Committee to Review Human Subjects (IRB). MFUA, in collaboration with WRAIR, drafted a subject contact letter with postcard response, a volunteer agreement affidavit (DA FORM 5303-R), and two versions--self-administered and nurse-administered--of a clinical interview form. These documents were reviewed by personnel in the Institute of Medicine's AIDS program. At its 31 March 1992 meeting, the Academy's IRB approved the MFUA proposal.

As a second step in the pilot study discussed earlier, addresses were sought for the 10% sample, minus the seven deaths (for obvious reasons) and the two "no records" (no further information available). For the 62 individuals in this second step, there were 41 records with a current address on record and 21 records without an address. Thus, about two-thirds of the sample found via VA records was presumed to be adequately located.

In anticipation of the need for further address tracing, a request was made to the National Institute for Occupational Safety and Health (NIOSH) for access to Internal Revenue Service address files. Through a specific legislative agreement, NIOSH reviews all such requests for studies of veterans and, if approved, forwards the requests to IRS. MFUA's request was reviewed by NIOSH personnel and was rejected. Typically, outside requests involve studies of military veterans who have been exposed to hazards in military service, and according to NIOSH personnel, our request did not fit these guidelines. In the upcoming year, another request will be sent to NIOSH, emphasizing that the Army treats exposure to HIV virus no differently than any other exposure that leads to medical disability.

In a 30 July 1992 meeting with WRAIR investigators, it was decided to send a list of subjects with addresses from the pilot study (see above) to Dr. Chung of Walter Reed Hospital to test the contact procedures. After further consultation, it was also decided to include additional data from the USAHDS file along with identifying and address data. When the names from the pilot study--selected from the earlier hard-copy listing--were compared to the USAHDS file, however, we discovered that some names on the earlier file did not appear on the later file; presumably some earlier LTFUs had actually been found. Thus, only 32 records were sent to Dr. Chung. MFUA has just recently learned that of the 12 Washington area names on this list, 7 were known to Dr. Chung as being actively followed up. Although this is admittedly quite a small sample, these very preliminary results indicate that there will be a need to screen putative LTFU subjects before an attempt to contact is actually made.

Data Management: security and confidentiality

Since this contract was signed, MFUA has obtained its own dedicated microcomputer file server. No other Institute of Medicine Divisions are given access to this machine, and access to the LTFU data files is thereby strictly controlled. In addition, identification data are stored separately from the file containing all other data, and the two files are linked together only when required for the purposes of the study. Finally, in submitting identified data to the VA to obtain hospitalization data, additional bogus controls were added to the request file (see above) in order to mask the HIV status of the subjects sent to VA.

Data Analysis and Dissemination

Other than the analysis of pilot study results, no data analysis has been done. Data analysis will be done in the upcoming year.

Future Plans

In the upcoming year, mortality and morbidity records follow-up will continue as noted above. The remaining LTFU subjects will be located and contacted, and data on these individuals obtained for analysis. Requests for access to data will gain be made to CDC and to NIOSH.

Based on the results from the small pilot sample, there is the likelihood that a high proportion of supposedly LTFU subjects are in actuality being actively followed. This presents two different problems. First, resources may be unwisely spent in tracing such subjects and in obtaining their morbidity records. Second, attempts to contact actively followed patients who are mistakenly thought to be lost-to-follow-up may cause a certain amount of consternation among those subjects. Before full-scale contacting is begun, a way must be found to insure that the LTFU status is as up to date as possible.

Two potential solutions are suggested for further discussion. First, the LTFU file taken from USAHDS should be updated periodically, and individuals who have dropped off should be noted on the LTFU roster. Second, Army medical care records, both inpatient and outpatient, should be checked to see whether there has been recent active contact of LTFU subjects with the Army medical care system.

Finally, the pace of the study is expected to pick up during the coming year. MFUA has hired an additional Ph.D. epidemiologist who will be working half-time on this study. This, along with additional MFUA operations staff who will be hired shortly, is expected to allow for faster progress.